UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,569	10/27/2003	Stefan Henke	01-1405	3543

28501 7590 06/23/2010

MICHAEL P. MORRIS
BOEHRINGER INGELHEIM USA CORPORATION
900 RIDGEBURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877-0368

EXAMINER	
PURDY, KYLE A	
ART UNIT	**PAPER NUMBER**
1611	

NOTIFICATION DATE	DELIVERY MODE
06/23/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

Office Action Summary	Application No.	Applicant(s)	
	10/694,569	HENKE ET AL.	
	Examiner	Art Unit	
	Kyle Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *21-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2 pages (1/22/2010)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of t/e previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/22/2010 has been entered.

Status of Application

2. The Examiner acknowledges receipt of the arguments filed on 01/22/2010.

3. Claims 1-20 and 25 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

4. Applicants arguments filed 01/22/2010 regarding the rejection of claims 1-19 and 25 made by the Examiner under 35 USC 103(a) over Bock et al. (US 6869948) in view of Faour et al. (US 2004/0204413) have been fully considered but they are not found persuasive.

5. Applicants arguments filed 01/22/2010 regarding the rejection of claim 20 made by the Examiner under 35 USC 103(a) over Bock et al. (US 6869948) in view of Faour et al. (US 2004/0204413) and in further view of Parikh (1997) have been fully considered but they are not found persuasive.

6. The rejection of claims 1-20 and 25 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 07/31/2009.

7. In regards to the 103(a) rejection, Applicant asserts the following:

A) The invention is directed to water soluble meloxicam granules, whereas the Examiner has stated that some of the ingredients of the art are water-insoluble. The rejection is therefore improper; and

B) Bocks granules form a dispersion whereas the granules of the present invention form a solution.

8. In response to A, Applicants claim to "water soluble meloxicam granules" have at least two different interpretations. First is that the water soluble feature is for the granule as a whole and inclusive to all ingredients. Second is that the water soluble feature is solely for the meloxicam granule itself, and not the entire composition. It's the position of the Examiner that the particles of Bock have water soluble meloxicam granules. Applicant is directed to Table 1 of Bock (pasted below).

TABLE 1

Saturation solubility of meloxicam and its salts in various dissolving media

	Solubility at ambient temperature [mg/100 ml]			
Medium	Meloxicam	Sodium salt	ammonium salt	meglumin salt
0.1 N hydrochloric acid (pH 1)	0.09	0.05	0.04	0.1
Buffer pH 4	0.05	0.02	0.02	0.04
Water (pH 7)	0.2	785	230	860
Buffer pH 7.4	About 100	635	285	1290

It's clear to the Examiner that the meloxicam granules alone are not water soluble. However, when formulated as a meglumine salt, they are soluble and would meet the limitation of Applicants claim of "water soluble meloxicam granules".

9. In response to B, this argument is not persuasive. Applicant is requested to point out to the Examiner where Bock teaches that their composition is intended for forming dispersions, rather

than solutions. The goal of Bock is to produce water soluble meloxicam granules for inclusion into tablets or capsules (see Examples 6 and 7).

Maintained Rejections, of Record
Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. **Claims 1-19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bock et al. (US 6869948) in view of Faour et al. (US 2004/0204413).**

12. Bock is directed to oral meloxicam compositions. A granule formulation is disclosed in Example 7. The meloxicam granules comprise meloxicam, sodium citrate, lactose (carrier) (see instant claims 1 and 13-16), polyvinylpyrrolidone (povidone; a binder) (see instant claims 1, 3 and 4). It is taught that the meloxicam may be a sodium or megluine salt (see claim 1; see instant claims 1 and 2). The ratio between meglumine and meloxicam is taught to be from 1.2:1 to 1:1.2 (see instant claims 18 and 19).The concentration of meloxicam in the granules is about 3.5% by weight (see Example 7; see instant claim 17).

13. Bock fails to teach the composition as comprising a sweetener and an optional flavorant. Moreover, Bock fails to teach 5g of their meloxicam granules as being capable of dissolving in 100 mL of demineralized water within 1 minute.

14. Faour is directed to pharmaceutical composition containing a COX-II inhibitor and a muscle relaxant which may be in the form of a granule. An exemplified COX-II inhibitor is

meloxicam (see claim 1). It is taught that the granular formulations are to comprise a flavorant such as apple and vanilla (see [0087]; see instant claims 9-12) and a sweetener such as a aspartame and saccharin (see [0074]; see instant claims 5-8). It is taught that these excipients are useful for including into such compositions to impart a sweetness and a pleasant flavor to the preparation.

15. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bock and Faour with a reasonable expectation for success in arriving at a water soluble granule composition comprising meloxicam meglumine, a binder, a sweetener, a carrier and an optional flavorant. Bock and the instant composition are essentially identical except for the lacking of the sweetener and optional flavorant, otherwise the compositions are identical. It is acknowledged that Bock does not teach 5 grams of their granules as possessing the ability to dissolve in 100 mL of water. However, because the compositions are essentially identical, except for the sweetener, one would expect both to have similar pharmacological and physical properties. The fact that Bock does not teach their granules as possessing such a property does not mitigate the applicability of teaching to the instant application. It is the position of the Examiner, absent any secondary evidence, that the granules of Bock possess similar dissolution properties as that instantly claimed as the formulas are sufficiently alike in make up See MPEP 2112.01. With respect to the inclusion of a flavorant and a sweetener in the granule composition, this is obvious. One would be motivated to include such ingredients to impart a nice flavor to the composition when consumed by the user. Therefore, a water soluble granule comprising meloxicam, a binder, a carrier, a sweetener and an optional flavorant is *prima facie* obvious to one of ordinary skill in the art at the time the

invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

16. **Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bock et al. (US 6869948) in view of Faour et al. (US 2004/0204413) and Parikh (Handbook of Pharmaceutical granulation Technology, 1st edition, 1997, 60-72; of record).**

17. Bock and Faour are relied upon for disclosure described in the rejection of claims 1-19 and 25 under 35 U.S.C. 103(a).

18. As discussed above, Bock teaches a granular composition which comprises meloxicam, megluime, povidone (binder) and lactose (carrier).

19. Bock fails to teach a composition which comprises meloxicam, meglumine, hydroxypropylmethylcellulose, povidone and glucose monohydrate (dextrose).

20. Fauor teaches that the carrier for their granular composition may be lactose or dextrose. Fauor also teaches that the binder for the granular composition can be povidone (see [0076] and [0077]). It is also taught that other known materials can be utilized in the particle formulation and combinations may be used.

21. Parikh is drawn to a variety of binders to be used in granulating granules. It is taught that binders are provided to provide a cohesive force to the granules. Binders include natural and synthetic polymers such as povidone and hydroxypropyl methylcellulose (HPMC).

22. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bock, Faour and Parikh with a reasonable expectation for success in arriving at a water soluble granule composition comprise meloxicam,

meglumine, HPMC, povidone and glucose monohydrate. Albeit none of the references teach a composition with such properties, all of the ingredients are commonly used in the formulation of pharmaceutical granules. For instance, as discussed above, carriers such as lactose and glucose (dextrose) are interchangeable and binders such HPMC and povidone can be used together or by themselves. It would have been obvious to a person of ordinary skill in the art to look at the art and arrive at a composition with the instantly claimed components. With respect to the glucose being in the monohydrated form, this is obvious. Glucose (dextrose) are naturally found in the monohydrated form, so this requirement would be well within the purview to an ordinary skilled artesian. Therefore, a composition comprising meloxicam, meglumine, povidone, HPMC and glucose monohydrate is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611
June 10, 2010

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611